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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,634	11/21/2006	Jozsef-Michel Geczy	06131	2059

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DENNISON, SCHULTZ & MACDONALD
1727 KING STREET
SUITE 105
ALEXANDRIA, VA 22314

EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
11/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,634	GECZY, JOZSEF-MICHEL	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 6 and 9-11 are pending examination.

Information Disclosure Statement

The information disclosure statement filed 10/04/2006 incorrectly lists the inventor names for 6,472,390 and 2003/045522 as Geczy and Stamler et al., respectively. This is incorrect as Geczy is the inventor of 2003/045522 and Stamler et al. is the inventor of 6,472,390.

Withdrawn rejections

Applicant's amendments and arguments filed 6/29/2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 6, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geczy (2003/0045522) in view of Grodzinska et al. (Journal of Drug Development, 1991) and in further view of Kinoshita et al. (Long-term effects of Molsidomine on Exercise Tolerance in patients with exertional angina pectoris, 1983).

Applicant's Invention

Applicant claims a method of attenuating development of atherosclerosis comprising administering molsidomine in a sustained release solid composition effective over 24 hours, daily, for a period of at least six months, containing between 14 and 24 mg of molsidomine. Claim 9 specifies the dosage as 16 mg/dose. Claims 11 and 12 specify the composition is administered to a patient suffering from angina pectoris.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Geczy teaches a sustained release oral galenical form of molsidomine for the treatment of all forms of angina for application in therapeutics(abstract). Claim 1 recites the drug form, wherein the sustained release oral composition effective over 24 hours has an in vitro dissolution rate, measured spectrophotometrically at 286 or 311 nm by the method described in the European Pharmacopoeia, 3rd Edition (or USP XXIV), at 50 rpm, in 500 ml of a 0.1 N HCl medium, at 37 degrees Celsius, of: 1-25% of molsidomine released after 1 hour, 20-35% of molsidomine released after 2 hours, 50-65%% of molsidomine released after 6 hours, >85% of molsidomine released after 18 hours, >90% of molsidomine released after 24 hours, the plasma peak of molsidomine obtained in vivo occurring 2.5 to 5 hours following the administration of said form, and having a value of between 25 and 40 ng/ml of plasma. The dosage is 14-24 mg/dose (Claim 2).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Geczy does not teach a method of attenuating development of atherosclerosis comprising administering molsidomine in a sustained release solid form daily for a period of at least 6 months. It is for this reason that Grodzinska et al. is joined.

Grodzinska et al. teach that atherosclerosis can be treated with molsidomine (abstract). The study showed improvement in the 20 male patients suffering from atherosclerosis during 2 and 4 weeks of treatment by activating the fibrinolytic system and inhibiting platelet aggregation. Grodzinska et al. do not teach molsidomine is administered for a period of at least 6 months. It is for this reason that Kinoshita et al. is joined.

Kinoshita et al. teach the long treating eight men with obstructive coronary artery disease and exertional angina pectoris long-term for 6 weeks. Subsequently, 4 of the seven patients were further placed on therapy for 6 months (page 1399).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Geczy, Grodzinska et al. and Kinoshita et al. to further include using molsidomine in a method of treating atherosclerosis. One would have been motivated to include the molsidomine because Grodzinska et al. teach that it is used to treat atherosclerosis by activating the fibrinolytic system and inhibiting platelet aggregation.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Geczy, Grodzinska et al. and Kinoshita et al. to further include using molsidomine over for a period of at least 6 months. One would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since Kinoshita et al. teach administering molsidomine for 6 months. Therefore, a physician treating a patient with atherosclerosis would have been motivated to adjust the length of administration to at least 6 months based on the individual needs of the patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616